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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,257	02/08/2002	Boyong Li	141-242A	9034

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,257	LI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Percel et al (US 2001/0046964 hereafter '964) in view of Shah et al (USPN 6,126,969 hereafter '969).

The '964 patent discloses a controlled release comprising multiple coated particles, (pellets, granules, etc.) comprising a drug core and a polymer coating (abstract). The drugs in the core comprise bupropion [0020]. Enteric polymers include cellulose acetate phthalate, pH-sensitive methacrylic acid-methamethacrylate and other commonly known enteric polymers

[0010]. The water insoluble pH-sensitive include ethylcellulose, polyvinyl acetate and insoluble Eudragit polymers [0011]. Due to the multiplicity of the pellets one set of particles will comprise the enteric polymer and another set of particles will comprise the insoluble polymers in their respective coating layers. The coated drug particles are collected into capsules [claims]. The reference is however silent to the inclusion of an immediate release drug portion. The inclusion of immediate release drug portions is known in the art in order to provide fast relief and pulse the remaining drug dosage over time. This can be seen in the '969 patent.

The '969 patent discloses a combination immediate/sustained release formulation, where uncoated or powdered drug particles are combined with coated drug particles in order to provide a pulsatile release profile (abstract). Uncoated drug particle are combined with the same drug only coated with enteric polymers (col. 4, lin. 29-38). The polymers useful for the coating include ethylcellulose and methacrylate copolymers (col. 4, lin. 59-col. 5, lin. 22). The active agents include erythromycin, verapamil and other common active agents, all also disclosed in the '964 patent as useful (col. 6, lin. 15-45). The active agents are present in amounts up to 650 mg (Examples). The formulation may be compressed into tablets (claims). It would have been obvious to include an immediate release portion to the coated particles of the '964 as seen in the '969 in order to provide a pulsatile release tot he formulation with an instant relief of symptoms followed by a metered response for a sustained period.

Regarding the specific release pharmokinetics it is the position of the Examiner that such limitation are functional limitations that are dependent on the compositional components of the instant claims. Since the prior art provides a formulation meeting these limitations, namely a pharmaceutical dosage form comprising an immediate release portion, and a first pellets

comprising an enteric polymer coating and a second pellet comprising a water insoluble polymer coating, the prior art must also meet the pharmokinetic limitations as well. A composition and its properties cannot be separated, and since the composition of the prior art provides the same components it must also inherent have the same functional limitations, specifically the Cmax, Tmax and *in vivo* release characteristics.

With these aspects in mind it would have been obvious to combine the immediate release portion of the '969 patent into the formulation of the '964 and provide an immediate release bupropion portion in order to provide a pulsatile release, providing immediate symptom relief followed by long term relief. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a stable pulsatile dosage useful in treating depression.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618